

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner:	Not Yet Assigned	Art Unit:	
Re:	Application of:	Benjamin OSHLACK, et al.	
Serial No.:		Not Yet Assigned	
Filed:		Herewith	
For:		<b>TAMPER-RESISTANT ORAL OPIOID AGONIST FORMULATIONS</b>	

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

November 4, 2003

S i r:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Forms PTO-1449, which is a copy of the Forms submitted in connection with the parent application, US Serial No. 09/781,08, for consideration by the Examiner in connection with the examination of the above-identified patent application.

Applicants also respectfully advise the Examiner of the following issued U.S. patents and co-pending U.S. patent applications which are commonly assigned to the owners of the instant application:

U.S. Patent Application Serial No. 10/244,783, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed September 16, 2002, which is a continuation application of U.S. Patent Application Serial No. 09/815,167, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed March 22, 2001, now U.S. Patent No. 6,475,494, issued on November 5, 2002, which is a continuation application of U.S. Patent Application Serial No. 09/218,662,

“OPIOID AGONIST/ANTAGONIST COMBINATIONS”, filed December 22, 1998, now U.S. Patent No. 6,277,384, issued on August 21, 2001.

U.S. Patent Application Serial No. 09/992,936, “OPIOID AGONIST/OPIOID ANTAGONIST/ACETAMINOPHEN COMBINATIONS”, filed November 5, 2001, which is a continuation application of U.S. Patent Application Serial No. 09/503,020, “OPIOID AGONIST/OPIOID ANTAGONIST/ACETAMINOPHEN COMBINATIONS”, filed February 11, 2002, now U.S. Patent No. 6,375,957, issued on April 23, 2002, which is a continuation-in-part of U.S. Patent Application Serial No. 09/218,662, “OPIOID AGONIST/ANTAGONIST COMBINATIONS”, filed December 22, 1998, now U.S. Patent No. 6,277,384, issued on August 21, 2001.

U.S. Patent Application Serial No. 09/815,162, “METHOD OF PREVENTING ABUSE OF OPIOID DOSAGE FORMS”, filed March 22, 2001, which is a continuation application of U.S. Patent Application Serial No. 09/218,663, “METHOD OF PREVENTING ABUSE OF OPIOID DOSAGE FORMS”, filed December 22, 1998, now U.S. Patent No. 6,228,863, issued on May 8, 2001.

U.S. Patent Application Serial No. 09/781,076, “CONTROLLED-RELEASE COMPOSITIONS CONTAINING OPIOID AGONIST AND ANTAGONIST”, filed February 8, 2001, pending.

U.S. Patent Application Serial No. 10/199,972, “PHARMACEUTICAL COMBINATIONS OF OXYCODONE AND NALOXONE”, filed July 18, 2002, pending.

U.S. Patent Application Serial No. 10/213,919, “OPIOID AGONIST FORMULATIONS WITH RELEASABLE AND SEQUESTERED ANTAGONIST”, filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,408, "SEQUESTERED ANTAGONIST FORMULATIONS", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/213,921, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST AND BITTERING AGENT", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,409, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST, AND IRRITANT", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,413, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST AND GELLING AGENT", filed August 6, 2002, pending.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii) the Examiner's attention is directed to Exhibit A attached herewith which contains the following:

(i) specifications and claims for pending application serial nos. 09/781,076; 10/199,972; 10/213,919; 10/214,408; and 10/213,921;

(ii) claims of pending application serial no. 10/244,783, which has the same specification as U.S. Patent No. 6,277,384, listed as reference AB on the Form PTO 1449 submitted with the Information Disclosure Statement of November 7, 2001;

(iii) claims of pending application serial no. 09/992,936, which has the same specification as U.S. Patent No. 6,375,957, listed as reference LD on enclosed Form PTO-1449;

(iv) claims of pending application serial no. 09/815,162, which has the same specification as U.S. Patent No. 6,228,863, listed as reference AA on the Form PTO 1449 submitted with the Information Disclosure Statement of November 7, 2001;

(v) claims of pending application serial nos. 10/214,413; and 10/214,409, which have the same specification as that of application serial no. 10/213,921, mentioned above in paragraph (i).

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. However, if it is determined that any additional fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,  
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By: 

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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
200.1133SERIAL NO.:  
09/781,081

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S):  
Oshlack, et al.FILING DATE:  
February 8, 2001GROUP:  
1615

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	3	9	6	5	2	5	6	06/22/1976	Leslie	424	22	
	AB	4	2	3	7	1	4	0	12/02/1980	Dudzinski	424	260	
	AC	4	8	8	6	9	1	0	12/28/1982	Leslie	536	56	
	AD	4	4	4	3	4	2	8	04/17/1984	Oshlack, et al.	424	22	
	AE	4	8	2	8	8	3	6	05/09/1989	Elger, et al.	424	419	
	AF	4	3	3	4	9	6	5	05/30/1989	Martani, et al.	424	488	
	AG	4	8	3	4	9	8	4	05/30/1989	Goldie, et al.	424	488	
	AH	4	8	8	8	9	8	5	05/30/1989	Elger, et al.	424	488	
	AI	4	8	4	4	9	0	7	07/04/1989	Elger, et al.	424	465	
	AJ	4	8	4	4	9	0	9	07/04/1989	Goldie, et al.	424	480	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AP	0	1	8	3	3	5	5	09/03/1986	Europe (A3)	A61K	31/615		
	AL	0	3	1	9	2	4	3	06/07/1989	Europe (A1)	A61K	31/485		
	AM	0	3	1	6	2	4	3	11/07/1990	Europe (A2)	A61K	31/485		
	AN	0	0	0	1	3	7	7	01/13/2000	WO	A61K	31/00		
	AO	9	0	0	4	9	6	5	05/17/1990	WO	A61K	31/485		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AP	Translation of previously submitted German patent application DE 43 25 465
AQ	Alvarez-Fuentes, et al., "Effectiveness of Repeated Administration of a New Oral Naltrexone Controlled-Release System on Morphine Analgesia", J. Pharm Pharmacol (2001), 53; pg. 1201-1205
AR	Alvarez-Fuentes, et al., "Preclinical Study of an Oral Controlled Release Naltrexone Complex in Mice"; J. Pharm Pharmacol (2000), 52; pg. 659-663

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
BA	4 8 4 4 9 1 0	07/04/1989	Leslie, et al.	424	494		
FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
BB							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
BC	Archer, Sydney; "Historical Perspective on the Chemistry and Development of Naltrexone"; Naltrexone: Research Monograph 28 (1980) pg. 3-9						
BD	Baum, et al., "The Impact of the Addition of Naloxone on the Use and Abuse of Pentazocine"; Public Health Reports (1987) Vol. 102, No. 4 pg. 426-429						
BE	Rapaka, et al., "Discovery of Novel Opioid Medications"; NIDA Research Monograph 147 (1995) pg. 53-83						
BF	Bloom, et al., "Clinical Studies with Naloxone/Methadone in a Ratio of 1:20"; 5th National Conference on Methadone Treatment (1973) Vol 2, pg. 1342 - 1349						
BG	Blachly, M.D., "Naloxone in Opiate Addiction"; Current Psychiatric Therapies (1976) pg. 209-213						
BH	Briscoe, et al., "Methoclocinnamox: Time Course of Changes in Alfentanil-Reinforced Responding in Rhesus Monkeys"; Psychopharmacology (2000) 148: pg. 393-399						
BI	Abstract of Bromm, et al., "A Sensitive Method to Evaluate Effects of Analgesics in Man"; Meth and Find Exptl Clin Pharmacol 5 (8) (1983) pg. 545-551						
BJ	Bullingham, et al., "Clinical Pharmacokinetics of Narcotic Agonist-Antagonist Drugs"; Clinical Pharm. (1983) 8: 332-343						
BK	Calimlim, et al., "Effect of Naloxone on the Analgesic Activity of Methadone in a 1:10 Oral Combination"; Clin Pharmacol and Thera (1974) Vol. 15; No. 6 pg. 556-564						
BL	Caruso, et al., "Methadone and Naloxone in Combination (Naldone®) for the Treatment of Heroin Addicts"; Bristol Laboratories, pg. 1336-1341F						
BM	Cherny, Nathan I., "Opioid Analgesics"; Drugs (1996) May; 51 (5) pg. 713-737						
BN	Chiang, et al., "Clinical Evaluation of a Naltrexone Sustained-Release Preparation"; Drug and Alcohol Dependence (1985) 16, pg. 1-8						
BO	Chiang, et al., "Kinetics of a Naltrexone Sustained-Release Preparation"; Clin. Pharmacol Thera (1984) Vol. 36, No. 5, pg. 704-708						
BP	Comer, et al., "Depot Naltrexone: Long-lasting Antagonism of the effects of heroin in humans"; Psychopharmacology (2002) 159; pg. 351-360						
BQ	Crabtree, et al., "Review of Naltrexone, a long-acting opiate antagonist"; Clinical Pharmacy, Vol 3 (1984) pg. 273-280						
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*EXAMINER INITIAL	CA	DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
		4	8	6	7	9	8	5	09/19/1989	Heafield, et al.	424	461	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
										YES	NO		
	CB												
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	CC	Crain et al., "Antagonists of excitatory opioid receptor functions enhance morphine's analgesic potency and attenuate opioid tolerance/dependence liability"; Dept. Of Neuroscience, Albert Einstein College of Medicine, Pain 82 (1999) pg. 1-11											
	CD	Crain et al., "Antagonists of excitatory opioid receptor functions enhance morphine's analgesic potency and attenuate opioid tolerance/dependence liability"; Dept. Of Neuroscience, Albert Einstein College of Medicine, Pain 84 (2000) pg. 121-131											
	CE	Fink, et al., "Naloxone in Heroin Dependence"; Clin Pharm and Therapeutics, Vol 9, No. 5; pg. 568-577											
	CF	Fishman, et al., "Disposition of Naloxone-7,8- <sup>3</sup> H in Normal & Narcotic-Dependent Men"; J. of Pharm. and Experimental Therapeutics (1973) Vol 187, No. 3, pg. 575-580											
	CG	Fraser, Albert D., et al., "Clinical Toxicology of Drugs Used in the Treatment of Opiate Dependency"; Clinical Toxicology 1, (1990) Vol 10, No. 2, pg. 375-386											
	CH	Freye, et al., "Effects of Tramadol and Tilidine/Naloxone on Oral-Caecal Transit & Pupillary Light Reflex"; Arzneim.-Forsch/Drug Res. 50 (I) (2000) pg. 24-30											
	CI	Fudala, et al., "Effects of Burpenorphine and Naloxone in Morphine-Stabilized Opioid Addicts"; Drug and Alcohol Dependence 50 (1998) pg. 1-8											
	CJ	Fudala, et al., "Human Pharmacology and Abuse Potential of Nalmefene"; Clin Pharm and Thera (1991) Vol 49, 3, pg. 300-306											
	CK	Gal, et al., "Prolonged Blockade of Opioid Effect with Oral Nalmefene"; Clin Pharmacol Ther. (1986) pg. 537-542											
	CC	Gerra, et al., "Clonidine and Opiate Receptor Antagonists in the Treatment of Heroin Addiction"; J. Substance Abuse Treatment (1995) Vol 12, 1, pg. 35-41											
	CM	Ghodse, et al., "Opioid analgesics and narcotic antagonists"; Side Effects of Drugs (2000) Annual 23, Ch. 8, pg. 96-113											
	CN	Glatt, William, M.D. FACP, "A New Method for Detoxifying Opioid-Dependent Patients"; J. Substance Abuse Treatment (1999) Vol 17, No 3, pg. 193-197											
	CO	Gold, et al., "Rapid Opioid Detoxification during General Anesthesia"; Anesthesiology (1999) Vol 91, No 6, 1639-1647											
	CM	Greenwald, et al., "Comparative Clinical Pharmacology of Short-Acting <i>Mu</i> Opioids in Drug Abusers"; J. Pharm. and Experimental Therapeutics (1996) Vol 277, No 3, pg. 1228-1236											
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DA	4 9 4 0 5 8 7	07/10/1990	Jenkins, et al.	424	480			
FOREIGN PATENT DOCUMENTS								
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
						YES NO		
DB								
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
DC	Gupta, et al., "Morphine Combined with Doxapram or Naloxone"; Anaesthesia (1974) Vol 29 pg. 33-39							
DD	Richter, et al., "Clinical Investigation on the Development of Dependence during Oral Therapy with Tramadol"; Arznieim-Forsch/Drug Res. 35 (No II) (1985) pg. 1742-1744							
DE	Rosen, et al., "Effect of Clonidine Pretreatment on Naloxone-Precipitated Opiate Withdrawal"; J. of Pharm. and Experimental Ther. (1996) Vol 276, No 3, pg. 1128-1135							
DF	Rosen, et al., "The effect of lamotrigine on naloxone-precipitated opiate withdrawal"; Drug and Alcohol Dependence (1998) Vol 52, pg. 173-176							
DG	Rosen, et al., "A pilot study of dextromethorphan in naloxone-precipitated opiate withdrawal"; European J. of Pharm. (1996) Vol 307, pg. 251-257							
DH	Schuh, et al., "Buprenorphine, Morphine and Naloxone Effects during Ascending Morphine Maintenance in Humans"; J. of Pharm. and Experimental Ther. (1996) Vol 278, 2, pg. 836-846							
DI	Schuh, et al., "Onset, magnitude and duration of opioid blockade produced by buprenorphine and naltrexone in humans"; Psychopharmacology (1999) Vol 145, pg. 162-174							
DJ	Stevens, et al., "Nonspecific Excitatory Effects of Morphine: Reverse-Order Precipitated Withdrawal and Dose-Dose Interactions"; Psychopharmacology (1981) Vol 75, pg. 210-211							
DK	Stine, et al., "Reduction of Opiate Withdrawal-like Symptoms by Cocaine Abuse during Methadone and Buprenorphine Maintenance"; Am. J. Drug Alcohol Abuse (1994) Vol 20, (4), pg. 445-458							
DL	Stine, et al., "Use of Drug Combinations in Treatment of Opioid Withdrawal"; J. of Clinical Psych. (1992) Vol 12, No. 3, pg. 203-209							
DM	Stoller, et al., "Effects of buprenorphine/naloxone in opioid-dependent humans"; Psychopharmacology (2001) Vol 154, pg. 230-242							
DN	Strain, et al., "Acute effects of buprenorphine, hydromorphone and naloxone in methadone-maintained volunteers"; J. of Pharm. and Experimental Ther. (1992) Vol 261, No. 3, pg. 985-993							
DO	Strain, et al., "Effects of buprenorphine versus buprenorphine/naloxone tablets in non-dependent opioid abusers"; Psychopharmacology (2000) Vol 148, pg. 374-383							
DP	Strain, et al., "Precipitated Withdrawal by Pentazocine in Methadone-Maintained Volunteers"; J. of Pharm. and Experimental Ther. (1993) Vol 267, No 2, pg. 624-634							
DQ	Tai, et al., "Naltrexone: An Antagonist Therapy for Heroin Addiction"; NIDA (1997) 5 pages							
DE	Umbricht, et al., "Naltrexone shortened opioid detoxification with buprenorphine"; Drug and Alcohol Dependence (1999) Vol 56, pg. 181-190							
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	EA	4	9	7	0	0	7	5	11/13/1990	Oshlack	424	451	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
										YES	NO		
	EB												
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	EC	Vaccarino, et al., "Endogenous Opiates: 1999"; Peptides 21 (2000) pg. 1975-2034											
	ED	Wang, et al., "Inverse agonists and neutral antagonists at $\mu$ opioid receptor (MOR): possible role of basal receptor signaling in narcotic dependence"; J. of Neurochemistry (2001) Vol 77, pg. 1590-1600											
	EE	Way, et al., "Responsivity to Naloxone during Morphine Dependence"; Annals New York Academy of Sciences, pg. 252-261											
	EF	Weinberg, et al., "Sublingual absorption of selected opioid analgesics"; Clin Pharm Ther (1988) Vol 44, No 3, pg. 335-342											
	EG	Wells, et al., "In Vivo Pharmacological Characterization of SoRI 9409, a Nonpeptidic Opioid $\mu$ -Agonists/ $\delta$ -Antagonist that Produces Limited Antinociceptive Tolerance and Attenuates Morphine Physical Dependence"; J. Pharm and Exper. Thera. (2001) Vol 297, No 2, pg. 597-605											
	EH	Wodak, Alex, "Drug Treatment for Opioid Dependence"; Australian Prescriber (2001) Vol 24, No 1, pg. 4-6											
	EI	Wright, et al., "Acute physical dependence in humans; repeated naloxone-precipitated withdrawal after a single-dose of methadone"; Drug and Alcohol Dependence (1991) Vol 27, pg. 139-148											
	EJ	Zhu, et al., "Naltrexone-precipitated morphine withdrawal in infant rat is attenuated by acute administration of NOS inhibitors but not NMDA receptor antagonists"; Psychopharmacology (2000) Vol 150, pg. 325-336											
	EK	Han, et al., "Mucoadhesive buccal disks for novel nalbuphine prodrug controlled delivery: effect of formulation variables on drug release and mucoadhesive performance"; International J. of Pharm (1999) Vol 177, pg. 201-209											
	EL	Handal, et al., "Naloxone"; Annals of Emergency Medicine (1983) Vol 12:7, pg. 438-445											
	EM	Harris, et al., "Buprenorphine and naloxone co-administration in opiate-dependent patients stabilized on sublingual buprenorphine"; Drug and Alcohol Dependence (2000) Vol 61, pg. 85-94											
	EN	Hawkes, et al., "Effect of an enteric-release formulation of naloxone on intestinal transit in volunteers taking codeine"; Aliment Pharm Ther (2001) Vol 15, pg. 625-630											
	EO	Högger, et al., "Comparison of tilidine/naloxone, tramadol and bromfenac in experimental pain: a double-blind randomized crossover study in healthy human volunteers"; International J. Clin Pharm and Ther (1999) Vol 37, No 8, pg. 377-385											
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	FA	4	9	9	7	1	3	6	01/22/1991	Kreek, et al.	514	282	
	FB	4	9	9	9	3	4	1	02/05/1991	Goldie, et al.	424	484	
	FC	5	0	7	1	6	4	6	12/10/1991	Malkowska, et al.	424	497	
	FD	5	0	9	1	1	8	9	02/25/1992	Heafield, et al.	424	457	
	FE	5	2	1	5	7	5	8	06/01/1993	Krishnamurthy	424	484	
	FF	5	2	2	6	3	3	1	07/13/1993	Thompson, et al.	73	865.9	
	FG	5	2	6	6	3	3	1	11/30/1993	Oshlack, et al.	424	468	

## FOREIGN PATENT DOCUMENTS

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													YES	NO
	FH													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	FI	Budd, Keith, "Clinical use of Opioid Antagonists"; Bailliere's Clinical Anesthesiology (1987) Vol 1, No 4, pg. 993-1011
	FJ	Crain, et al., "Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic cotreatment"; Proc. Natl. Acad. Sci (1995) Vol 92, pg. 10540-10544
	FK	Howes, et al., "The Pharmacology of TR5109, a New Narcotic Agonist/Antagonist Analgesic"; NIDA Research (1979) pg. 99-105
	FL	Leeling, et al., "Disposition and metabolism of codorphone in the rat, dog and man"; Drug Metabolism and Disposition (1982) Vol 10, No 6, pg. 649-653
	FM	Amass, et al., "Efficacy of daily and alternate-day dosing regimens with the combination buprenorphine-naloxone tablet"; Drug and Alcohol Dependence (2000) Vol 58, pg. 143-152
	FN	Hussain, et al., "Buccal and oral bioavailability of naloxone and naltrexone in rats"; (1987) Vol 36, pg. 127-130
	FO	Jasinski, et al., "The human pharmacology and abuse potential of N-allylnoroxymorphone naloxone"; J. of Pharm and Exper Thera (1967) Vol 157, No. 2, pg. 420-426
	FP	Jones, et al., "Nalmefene: blockade of intravenous morphine challenge effects in opioid abusing humans"; Drug and Alcohol Dependence (2000) Vol 60, pg. 29-37
	FP	Kanof, et al., "Clinical Characteristics of Naloxone-Precipitated Withdrawal in Human Opioid-Dependent Subjects"; J. of Pharm and Exper Thera (1992) Vol 260, No. 1, pg. 355-363
	FP	King, et al., "Naltrexone Biotransformation and Incidence of Subjective Side Effects: A Preliminary Study"; Alcoholism: Clin and Exp Res (1997) Vol 21, No. 5, pg. 906-909

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<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	GA	5 2 8 6 4 9 3	02/15/1994 Oshlack, et al.	424	468		
	GB	5 3 2 4 3 5 1	06/28/1994 Oshlack, et al.	106	153		
	GC	5 3 3 6 0 9 1	08/09/1994 Raffa, et al.	514	629		
	GD	5 3 5 6 4 6 7	10/18/1994 Oshlack, et al.	106	153		
	GE	5 4 1 1 7 4 5	05/02/1995 Oshlack, et al.	424	456		
	GF	5 4 6 0 8 2 6	10/24/1995 Merrill, et al.	424	470		
	GG	5 4 7 2 7 1 2	12/05/1995 Oshlack, et al.	424	480		
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	GH	8 7 0 1 2 8 2	03/12/1987 WO	A61K	31/485		
	GI	0 1 3 2 1 8 0	05/10/2001 WO (A2)	A61K	31/485		
	GJ	0 1 6 8 0 9 0	09/20/2001 WO (A2)	A61K	31/00		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
GK	Kogan, et al., "Estimation of the Systemic Availability and other Pharmacokinetic Parameters of Naltrexone in Man after Acute and Chronic Oral Administration"; Res. Comm. in Chem. Path. and Pharm (1977) Vol 18, No. 1, pg. 29-34						
GL	Kosten, Thomas R., M.D., "Buprenorphine for Benzodiazepine-Abusing Heroin Addicts"; Amer J. of Psychiatry (1994) Vol 1, pg. 151						
GM	Kosten, et al., "Opioid antagonist challenges in buprenorphine maintained patients"; Drug and Alcohol Dependence (1990) Vol 25, pg. 73-78						
GN	Kurland, et al., "Naloxone and the Narcotic Abuser: A Controlled Study of Partial Blockade"; Inter. J. of the Addictions (1974) Vol 9, No. 5, pg. 663-672						
GO	Lee, et al., "Nalbuphine Coadministered with Morphine Prevents Tolerance and Dependence"; Anesth Analg (1997) Vol 84, pg. 810-815						
GP	Lehmann, et al., "Influence of Naloxone on the Postoperative Analgesic and Respiratory Effects of Buprenorphine"; Eur J. Clin. Pharm. (1988) Vol 34, 343-352						
GQ	Levine, et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J Clin Invest. (1988) Vol 82, pg. 1574 - 1577						
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APPLICANT(S):  
Oshlack, et al.FILING DATE:  
February 8, 2001GROUP:  
1615

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	HA	5	4	7	8	5	7	7	12/26/1995	Sackler, et al.	424	489	
	HB	5	5	0	0	2	2	7	03/19/1996	Oshlack, et al.	424	476	
	HC	5	5	0	8	0	4	2	04/16/1996	Oshlack, et al.	424	468	
	HD	5	5	0	8	0	4	3	04/16/1996	Krishnamurthy	424	484	
	HE	5	5	4	9	0	1	2	08/27/1996	Oshlack, et al.	424	468	
	HF	5	5	5	2	4	2	2	09/03/1996	Gauthier, et al.	514	368	
	HG	5	5	9	1	4	5	2	01/07/1997	Miller, et al.	424	468	
	HH	5	6	0	1	8	4	5	02/11/1997	Buxton, et al.	424	495	
	HI	5	6	2	2	7	2	2	04/22/1997	Knott, et al.	424	494	
	HJ	5	6	3	9	4	7	6	06/17/1997	Oshlack, et al.	424	468	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	HK													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	HL	Loimer, et al., "Combined Naloxone/Methadone Preparations for Opiate Substitution Therapy"; J. of Substance Abuse Treatment (1991) Vol 8, pg. 157-160											
	HM	Martin, et al., "Bioavailability Investigation of a New Tilidine/Naloxone Liquid Formulation Compared to a Reference Formulation"; Arzneim.-Forsch./Drug Res. (1999) Vol 49, pg. 599-607											
	HN	Martin, et al., "Demonstration of Tolerance to and Physical Dependence on N-allylnormorphine (Nalorphine)"; J. of Pharm and Exper Thera (1965) Vol 150, No. 3, pg. 437-442											
	HO	Mendelson, et al., "Buprenorphine and naloxone combinations: the effects of three dose ratios in morphine-stabilized, opiate-dependent volunteers"; Psychopharmacology (1999) Vol 141, pg. 37-46											
	HP	Mendelson, et al., "Buprenorphine and Naloxone Interactions in Methadone Maintenance Patients"; Society of Biological Psychiatry (1997) Vol 41, pg. 1095-1101											
	HO	Nutt, et al., "Methadone-naloxone mixtures for use in methadone maintenance programs"; Clin Pharma and Thera, Vol 15, No. 2, pg. 156-166											
	HR	Parwatikar, et al., "Methadone-naloxone in combination for the treatment of heroin addicts"; Clin Pharm and Thera, Vol 14, No. 6, pg. 941-948											

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	IA	5	6	5	6	2	9	5	08/12/1997	Oshlack, et al.	424	468		
	IB	5	6	7	0	1	7	2	09/23/1997	Buxton, et al.	424	495		
	IC	5	6	7	2	3	6	0	09/30/1997	Sackler, et al.	424	490		
	ID	5	6	8	1	5	8	5	10/28/1997	Oshlack, et al.	424	494		
	IE	5	2	6	3	4	5	2	06/09/1998	Miller, et al.	514	282		
	IF	5	7	8	0	4	7	0	07/14/1998	Kim	514	282		
	IG	5	8	1	1	1	2	0	09/22/1998	Krishnamurthy	424	498		
	IH	5	6	3	4	4	7	7	11/10/1998	Mioduszewski	514	282		
	II	5	8	4	3	4	8	0	12/01/1998	Miller, et al.	424	484		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	IJ													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	IK	Parwartikar, et al., "Naloxone-Methadone Combination for the Treatment of Opiate Dependence"; Missouri Institute of Psychiatry, pg. 1350-1354												
	IL	Pitts, et al., "Antinociceptive and Response Rate-Altering Effects of <i>Kappa</i> Opioid Agonists, Spiradoline, Enadoline and U69,593, Alone and in combination with Opioid Antagonists in Squirrel Monkeys"; J. Pharm and Exper Thera (1994) Vol 271, No. 3, pg. 1501-1508												
	IM	Preston, et al., "Buprenorphine and Naloxone alone and in combination in opioid-dependent humans"; Psychopharmacology (1988) Vol 94, pg. 484-490												
	IN	Preston, et al., "Differential Naltrexone Antagonism of Hydromorphone and Pentazocine Effects in Human Volunteers"; J. Pharm and Exper Thera (1993) Vol 264, No. 2, pg. 813-823												
	IO	Preston, et al., "Effects of Sublingually given naloxone in opioid-dependent human volunteers"; Drug and Alcohol Dependence (1990) Vol 25, pg. 27-34												
	IP	Bigelow, et al., "Abuse Liability Assessment of Buprenorphine-Naloxone Combinations"; Dept. of Psychiatry and Behavioral Sciences - The Johns Hopkins University School of Medicine, pg. 145-149												
	IQ	Wikler, et al., 'N-Allylnormorphine: Effects of single doses and precipitation of acute "Abstinence Syndromes" during addiction to morphine, methadone or heroin in man (post-addicts)'; N-Allylnormorphine During Narcotic Addiction (1953) pg. 8-20												
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	JA	5	8	4	9	2	4	0	12/15/1998	Miller, et al.	264	460	
	JB	5	8	6	9	0	9	7	02/09/1999	Wong, et al.	424	473	
	JC	5	8	7	9	7	0	5	03/09/1999	Heafield, et al.	424	464	
	JD	5	8	9	1	4	7	1	04/06/1999	Miller, et al.	424	468	
	JE	5	9	0	8	8	4	8	06/01/1999	Miller, et al.	514	282	
	JF	5	9	5	8	4	5	2	09/28/1999	Oshlack, et al.	424	457	
	JG	5	9	5	8	4	5	9	09/28/1999	Chasin, et al.	424	490	
	JH	5	9	6	5	1	6	1	10/12/1999	Oshlack, et al.	424	457	
	JI	5	9	6	5	1	6	3	10/12/1999	Miller, et al.	424	468	
	JJ	5	9	6	8	5	5	1	10/19/1999	Oshlack, et al.	424	456	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	JK													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	JL	Zaks, et al., "Naloxone Treatment of Opiate Dependence"; JAMA (1971) Vol 215, No. 13, pg. 2108-2110
	JM	Barton, et al., "Intranasal Administration of Naloxone by Paramedics"; Prehospital Emergency Care (2002) Vol 6, No. 1, pg. 54-58
	JN	Blachly, Paul, H., M.D., "Naloxone in Opiate Addiction"; Current Psychiatric Therapies (1976) pg. 209-213
	JO	Bashaw, et al., "Relative bioavailability of controlled-release oral morphine sulfate during naltrexone blockade"; Inter J. of Clin Pharm and Thera (1995) Vol 33, No. 9, 524-529
	JP	Jasinski, D.R., "Assessment of the Abuse Potential of Morphinelike Drugs (Methods Used in Man)"; Drug Addiction (1977) pg. 197-258
	JQ	Johnson, et al., "Buprenorphine and Naloxone for Heroin Dependence"; Substance Use Disorders (2000) pg. 519-526
	JR	Strain, et al., "Opioid antagonist effects of dezocine in opioid-dependent humans"; Clin Pharm and Thera (1996) Vol 60, No. 2, pg. 206-217

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Oshlack, et al.FILING DATE:  
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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	KA	6	0	2	4	9	8	2	02/15/2000	Oshlack, et al.	424	476	
	KB	6	0	6	8	8	5	5	05/30/2000	Leslie, et al.	424	468	
	KC	6	0	7	7	5	3	2	06/20/2000	Malkowska, et al.	424	457	
	KD	6	0	7	7	5	3	3	06/20/2000	Oshlack, et al.	424	461	
	KE	6	1	0	5	2	5	8	08/15/2000	Simon	424	449	
	KF	6	1	0	3	2	6	1	08/15/2001	Chasin, et al.	424	459	
	KG	6	1	4	3	3	2	2	11/07/2000	Sackler, et al.	424	459	
	KH	6	1	4	3	3	2	8	11/07/2000	Heafield, et al.	424	449	
	KI	6	1	6	2	4	6	7	12/19/2000	Miller, et al.	424	449	
	KJ	6	2	1	0	7	1	4	04/03/2001	Oshlack, et al.	424	476	
	KK	6	2	5	4	8	8	7	07/03/2001	Miller, et al.	424	468	
	KL	6	2	6	1	5	9	9	07/17/2001	Oshlack, et al.	424	457	
	KM	6	2	0	4	1	9	5	09/25/2001	Oshlack, et al.	424	457	

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	KQ	0	1	9	3	8	5	2	12/13/2001	WO (A2)	A61P	31/00		

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KR	Preston, et al., "Abuse liability studies of opioid agonist-antagonists in humans"; Drug and Alcohol Dependence (1991) Vol 28, pg. 49-82
KS	Brennscheidt, et al., "Pharmacokinetics of Nortilidine and Naloxone after Administration of Tilidine/Naloxone Solution or Tilidine/Naloxone Sustained Release Tablets"; Arzneimittel-Forsch/Drug Res. (2000) Vol 50, pg. 1015-1022

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	LD	6	3	7	5	9	5	7	04/23/2002	Kaiko, et al.	424	400		
	LE	6	3	8	7	4	0	4	05/14/2002	Oshlack, et al.	424	480		
	LF	6	3	9	9	0	9	6	06/04/2002	Miller, et al.	424	464		
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	LM													
	LN													
	LO													
	LP													
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Curtis Wright et al.FILING DATE:  
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	AA	5	9	9	8	4	3	4	12/99	Mitch et al.	514	210.16	
	AB	5	9	7	2	9	5	4	10/99	Foss	514	282	
	AC	5	9	6	8	5	4	7	10/99	Reder et al.	424	449	
	AD	5	9	4	2	2	4	1	8/99	Chasin et al.	424	426	
	AE	5	8	8	0	1	3	2	3/99	Hill	514	282	
	AF	5	8	6	6	1	6	4	2/99	Kuczynski et al.	424	472	
	AG	5	8	6	0	9	5	0	1/99	Demopoulos et al.	604	49	
	AH	5	8	5	8	0	1	7	1/99	Demopoulos et al.	604	890.1	
	AI	5	7	8	7	1	2	5	6/98	Crain et al.	514	282	
	AJ	5	6	3	3	2	5	8	5/97	Qin et al.	514	282	
	AK	5	6	2	4	9	3	2	4/97	Qin et al.	514	282	

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	AM	29	7	1	9	7	0	4	2/97	DE	A61K	31/485		
	AN	4	3	2	5	4	6	5	2/95	DE	A61K	31/485	X	
	AQ	2	2	2	2	0	3	9	11/72	DE	A61K	27/00		
	AP	0	9	1	3	1	5	2	6/99	EP	A61K	31/485		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AQ	Abstract, Cancer Chemother Pharmacol (1998); 42(4):287-91.
	AR	Yuan et al., Drug and Alcohol Dependence (1998); 52:161-165.
	AS	Gan et al., "Opioid-Sparing Effects of a Low-Dose Infusion of Naloxone in Patient-Administered Morphine Sulfate," Anesthesiology (1997), 87(5):1075-1080.

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	BA	5	6	1	8	6	0	1	4/97	Khanna et al.	514	399		
	BB	5	5	8	5	3	4	8	12/96	Crain et al.	514	12		
	BC	5	5	8	0	8	7	8	12/96	Crain et al.	514	282		
	BD	5	5	7	8	7	2	5	11/96	Portoghese et al.	546	35		
	BE	5	5	7	4	0	5	2	11/96	Rose et al.	514	343		
	BF	5	5	5	6	8	3	8	9/96	Mayer et al.	514	25		
	BG	5	5	3	4	4	9	2	7/96	Aston et al.	514	608		
	BH	5	5	1	4	6	8	0	5/96	Weber et al.	514	249		
	BI	5	5	1	2	5	7	8	4/96	Crain et al.	514	282		
	BJ	5	5	0	2	0	5	8	3/96	Mayer et al.	514	249		
	BK	5	4	6	8	3	6	2	1/96	Kitchell et al.	424	426		
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	BP	9	6	3	5	8	7	9	8/98	WO	A61K	31/485		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	BQ	Shen et al., "Ultra-Low Doses of Naltrexone or Etorphine Increase Morphine's Antinociceptive Potency and Attenuate Tolerance/Dependence in Mice," Brain Research (1997), 757:176-190.												
	BR	Yuan et al., Clinical Trials and Therapeutics (1997), 61:467-475.												
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	CA	5	4	7	2	9	4	3	12/95	Crain et al.	514	12		
	CB	5	4	5	7	7	0	0	10/95	Portoghese et al.	546	35		
	CC	5	4	2	6	1	1	2	6/95	Zagon et al.	514	282		
	CD	5	3	7	6	6	6	2	12/94	Ockert	514	282		
	CE	5	3	5	6	9	0	0	10/94	Bihari et al.	514	282		
	CF	5	3	5	2	6	8	3	10/94	Mayer et al.	514	289		
	CG	5	3	5	2	6	8	0	10/94	Portoghese et al.	514	279		
	CH	5	3	2	1	0	1	2	6/94	Mayer et al.	514	25		
	CI	5	3	1	7	0	2	2	5/94	Borsodi et al.	514	282		
	CJ	5	3	1	6	7	5	9	5/94	Rose et al.	424	10		
	CK	5	2	7	3	7	6	0	12/93	Oshlack et al.	424	486		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	CL	9	7	3	3	5	6	6	9/97	WO	A61K	9/20		
	CM	9	6	0	2	2	5	1	2/96	WO	A61K	31/485		
	CN	9	5	0	3	8	0	4	2/95	WO	A61K	31/485		
	CO	9	4	0	6	4	2	6	3/94	WO	A61K	31/46		
	CP	8	3	0	3	1	9	7	9/83	WO	A61K	9/22		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	CQ	Mendelson J., et al, "Buprenorphine and Naloxone Interactions in Opiate-Dependent Volunteers," Clin. Phar. Ther. (1996), 60:105-114.												
	CR	Walsh et al., "Effects of Naltrexone on Response to Intravenous Cocain, Hydromorphone and their Combination in Humans," (1996).												
EXAMINER										DATE CONSIDERED				
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<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): Curtis Wright et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	DA	5	2	5	6	6	6	9	10/93	Askanazi et al.	514	282		
	DB	5	2	3	6	7	1	4	8/93	Lee et al.	424	449		
	DE	5	2	2	5	4	4	0	7/93	London et al.	514	535		
	DD	5	1	4	9	5	3	8	9/92	Granger et al.	424	449		
	DE	5	1	0	2	8	8	7	4/92	Goldberg	514	282		
	DF	5	0	9	6	7	1	5	3/92	Sinclair	424	449		
	DG	5	0	8	6	0	5	8	2/92	Sinclair et al.	514	282		
	DH	5	0	7	5	3	4	1	12/91	Mendelson et al.	514	282		
	DI	4	9	3	5	4	2	8	6/90	Lewis	514	282		
	DJ	4	8	8	9	8	6	0	12/89	Rzeszotarski et al.	514	282		
	DK	4	8	8	2	3	3	5	11/89	Sinclair	514	282		
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	DL													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	DM	Chih-Cheng Chien, Neuroscience Letters 190 (1995), 137-139.												
	DN	Crain et al., "Ultra-Low Concentrations of Naloxone Selectively Antagonize Excitatory Effects of Morphine on Sensory Neurons, Thereby Increasing Its Antinociceptive Potency and Attenuating Tolerance/Dependence During Chronic Cotreatment," Proc. Natl. Acad. Sci. USA (1995), 92:10540-10544.												
	DO	Hanson, Analgesic, Antipyretic and Anti-Inflammatory Drugs in Remington's Science and Practice of Pharmacy (1995), 2:1207.												
	DP	Physician's Desk Reference 48 <sup>th</sup> Ed. (1994) Montvale, NJ, 2120-2121.												
	DQ	Foss et al., J. Clin Pharmacol (1993), 33:747-751.												
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	EA	4	8	7	3	0	7	6	10/89	Fishman et al.	412	10			
	EB	4	8	6	1	7	8	1	8/89	Goldberg	514	282			
	EC	4	8	6	1	5	9	8	8/89	Oshlack et al.					
	ED	4	8	0	6	5	5	8	2/89	Wuest et al.	514	381			
	EE	4	8	0	6	5	4	3	2/89	Choi	514	464			
	EF	4	8	0	6	3	4	1	2/89	Chien et al.	424	448			
	EG	4	8	0	3	2	0	8	2/89	Pasternak	514	282			
	EH	4	7	8	5	0	0	0	11/88	Kreek et al.	514	282			
	EI	4	7	6	9	3	7	2	9/88	Kreek et al.	514	282			
	EJ	4	7	6	0	0	6	9	2/89	Rzeszotarski et al.	514	282			
	EK	4	7	3	0	0	4	8	3/88	Portoghese et al.	546	45			
FOREIGN PATENT DOCUMENTS															
		DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
														YES	NO
	EL														
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
	EM	Holmes et al., Anesth. Analg. (1993), 77:1166-73.													
	EN	Miaskowski et al., Brain Research (1992), 596:41-45.													
	EO	Weinhold et al., "Buprenorphine Alone and In Combination with Naltrexone in Non-Dependent Humans," Drug and Alcohol Dependence (1992), 30:263-274.													
	EP	Cappel et al., Pharma. Bioch. & Behav. (1989), 34:425-427.													
	EQ	Vaccarino et al., Pain (1989), 36:103-109.													
	ER	Gonzalez et al., "Naltrexone: A Review of its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Efficacy in the Management of Opioid Dependence," Drugs (1988), 35:192-213.													
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	FA	4	7	1	9	2	1	5	1/88	Goldberg	514	282		
	FB	4	6	6	1	4	9	2	4/87	Lewis et al.	514	282		
	FC	4	6	6	8	3	7	6	4/86	Pasternak	514	282		
	FD	4	5	8	2	8	3	9	4/86	Lewis et al.	514	282		
	FE	4	5	7	3	9	9	5	3/86	Chen et al.	604	896		
	FF	4	4	6	4	3	7	6	8/84	Hussain et al.	424	260		
	FG	4	4	5	7	9	3	3	7/84	Gordon et al.	424	282		
	FH	4	4	5	1	4	7	0	8/84	Ganti	424	260		
	FI	4	4	6	1	6	7	2	8/83	Portoghese et al.	424	260		
	FJ	4	1	7	6	1	8	6	11/79	Goldberg	424	260		
	FK	3	9	6	6	9	4	0	6/76	Pachter et al.	424	260		
<b>FOREIGN PATENT DOCUMENTS</b>														
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													YES	NO
	FL													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	FM	Sunshine, et al., "Analgesic Efficacy of Pentazocine Versus a Pentazocine-Naloxone Combination Following Oral Administration," Clin. J. Pain (1988), 4:35-40.												
	FN	Wang et al., "Crossover and Parallel Study of Oral Analgesics," J. clin. Pharmacol (1981), 21:162-168.												
	FO													
	FP													
	FQ													
	FR													
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*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	GA	3	8	7	9	5	5	5	4/75	Pachter et al.	424	260		
	GB	3	7	7	3	9	5	5	11/73	Pachter et al.	424	260		
	GE	3	6	7	6	5	5	7	7/72	Lachman et al.	424	260		
	GD	3	4	5	3	6	5	7	2/70	Lewenstein et al.	424	260		
	GE	3	3	3	7	9	5	0	7/67	Blumberg et al.	260	285		
	GF	2	7	7	6	5	6	9	11/56	Fromherz et al.	167	65		
	GG													
	GH													
	GI													
	GJ													
	GK													
<b>FOREIGN PATENT DOCUMENTS</b>														
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													YES	NO
	GL													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	GM													
	GN													
	GO													
	GP													
	GQ													
	GR													
	GS													
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FILING DATE: February 8,  
2001

GROUP: 1615

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6	2	2	8	8	6	3	05/08/01	Palermo et al.	514	282	
	AB	6	2	7	7	3	8	4	08/21/01	Kaiko et al.	424	400	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AC	WO	98	2	5	6	1	3	06/18/98	EPO	A61K	31/485	Abstract	
	AD	WO	00	3	8	6	4	9	07/06/00	EPO	A61K	9/00	Abstract	

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AE	Press Release entitled "International Patent Application To Be Published on Abuse-Resistant Pain Reliever Being Developed by Purdue Pharma" August 8, 2001.
AF	Paronis, et al., Increased Analgesic Potency of Mu Agonists after Continuous Naloxone Infusion in Rats, J Pharm. Exper. Ther. 1991 259(2) pg 582-589
AG	Yoburn, et al., Supersensitivity to Opioid Analgesics Following Chronic Opioid Antagonist Treatment: Relationship to Receptor Selectivity, Pharmacol. Bio. Beh. 1995 51 (2) pg 535-539
AH	Crain, et al., Acute thermal hyperalgesia elicited by low-dose morphine in normal mice is blocked by ultra-low-dose naltrexone, unmasking potent opioid analgesia, Brain Res. 2001 888 pg 75-82
AI	Zhang, et al., Down-Regulation of $\mu$ -Opioid Receptors in Rat and Monkey Dorsal Root Ganglion Neurons and Spinal Cord After Peripheral Axotomy, Neuroscience 1998 82, pg 223-240
AJ	Abdulla, et al., Axotomy reduces the effect of analgesic opioids yet increases the effect of nociceptin on dorsal root ganglion neurons, J. Neuro Sci 1998 18, pg 9685-9694
AK	Di Giannuario, et al., Orphanin FQ reduces morphine-induced dopamine release in the nucleus accumbens: a microdialysis study in rats, Neurosci. Lett. 1999 272, pg 183-186
AL	Ciccocioppo, et al., Effect of nociceptin/orphanin FQ on the rewarding properties of morphine, Eur. J. Pharmacol. 2000 404, pg 153-159
AM	
AN	

EXAMINER

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES      NO
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AA	Benfey, Function of Myocardial $\alpha$ -ADRENOCEPTORS: Life Sciences (1982) Vol. 31 pg 101-112					
	AB	Levine, et al., Potentiation of Pentazocine Analgesia by Low-dose Naloxone: J. Clin. Invest. (1988) Vol. 82 pg. 1574-1577					
	AC	Yoburn, et al., Opioid Antagonist-induced Receptor Upregulation: Effects of Concurrent Agonist Administration, (1994) (Publication Date): Brain Research Bulletin, Vol. 33 pg 237-240					
	AD	Bunzow, et al., Molecular cloning and tissue distribution of a putative member of the rat opioid receptor gene family that is not a $\mu$ , $\delta$ or $\kappa$ opioid receptor type: FEBS Letters 347 (1994) pg. 284-288					
	AE	Mollereau, et al., ORL1, a novel member of the opioid receptor family: Cloning, functional expression and localization: FEBS Letters 341 (1994) pg. 33-38					
	AF	Wang, et al., cDNA cloning of an orphan opiate receptor gene family member and its splice variant: FEBS Letters 348 (1994) 75-79					
	AG	Suzuki, et al., Morphine conditioned place preference after chronic treatment with naloxone in the rat: Research Communications in Substances of Abuse. (1991) Vol. 12, No. 3 pg. 119-131					
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